

Notice of Allowability	Application No.	Applicant(s)	
	09/869,564	MARKHAM ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/10/2004.
2. ☒ The allowed claim(s) is/are claims 1, 3-6, 8-9, 17, 36, 38-40, 43-48 (final claims 1-18).
3. ☒ The drawings filed on 21 June 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>8/6/2001</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

REASONS FOR ALLOWANCE

The applicant's response filed June 10, 2004 has been entered. Claims 1, 3-6, 8-9, 17, 36, 38-40, and 43-48 are pending.

1. The following is an examiner's statement of reasons for allowance:

Concerning claims 1, 3-6, 8-9, 17, 38-40, 43-46, and 48, no prior art has been found teaching or suggesting the isolated nucleic acid molecule which encodes a tissue repair protein comprising a nucleotide sequence which hybridizes to a nucleic acid sequence shown in SEQ ID NO: 1 under high stringency condition, the method of diagnosing orofacial clefting in a patient via detecting expression of a nucleic acid shown in SEQ ID NO: 1 and a mutation in a nucleic acid sequence shown in SEQ ID NO: 1 and the delivery vehicle and the pharmaceutical composition comprising the isolated nucleic acid.

Concerning claims 36, and 47, no prior art has been found teaching or suggesting the isolated nucleic acid encoding a tissue repair protein comprising a nucleotide sequence shown in SEQ ID NO: 39 which hybridizes to DNA under stringent condition.

The closest reference is the patent of Derynck et al. (5,482,851, issued Jan. 1996). Derynck et al. disclose nucleic acid sequence encoding TGF- β from human and porcine (See the Abstract and fig. 4a - 4c). The nucleic acid sequence of TGF- β is useful in diagnosis and identification of TGF- β (See the Abstract) and the TGF- β has been used for wound healing (See column 1, lines 31-33 and column 14, lines 41-44). Derynck et al. do not disclose the isolated nucleic acid molecule which encodes a tissue repair protein comprising a nucleotide sequence which hybridizes to a nucleic acid sequence shown in SEQ ID NO: 1 under high stringency condition.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. Tung*
September 24, 2004

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

9/27/04